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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,616	07/27/2000	Lei Yu	INDA:005USD1	1049

7590

12/31/2002

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EXAMINER
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LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/31/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/626,616

Applicant(s)

YU, LEI

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 83-101 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 83-85 is/are allowed.
- 6) ☒ Claim(s) 86-90, 92-99 and 101 is/are rejected.
- 7) ☒ Claim(s) 91 and 100 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***1. Formal Matters***

- A. Amendment F, filed 9/30/02, has been entered into the record.
- B. Claims 83-101 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Specification***

- A. The objection of the specification has been withdrawn since Applicants have amended the title to more closely reflect the claimed subject matter.
- B. The objection to the specification has been withdrawn since Applicants have amended the first line of the specification to recite the proper continuing data in the first line of the specification.
- C. The objection to the specification has been withdrawn since Applicants have renumbered the pages of the specification starting at page 169.

### ***3. Claim Objections***

- A. All objections to the claims have been withdrawn in view of Applicants' arguments, or amendments to the claims.

### ***4. Claim Rejections - 35 USC § 112, first paragraph – written description***

- A. Claims 86-90, 92-99 and 101 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action dated 5/30/02. Applicant argues that the claimed invention is drawn toward a process of screening a candidate substance for its ability to bind a mu opioid receptor and not to the receptor itself. Therefore, the amino acids necessary to convey a mu opioid receptor function should not be an issue as it relates to written description. Applicant argues that, in providing written description, one must describe the claimed invention sufficiently to show that the inventor had possession of the claimed invention and that Applicant was in possession of an opioid receptor comprising at least 35 contiguous nucleotides of SEQ ID NO:7 including guanine 389. Applicant

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also argues that the binding characteristics are irrelevant since antibodies would be expected to bind to the receptor.

These arguments have been considered, but are not deemed persuasive. First, though Applicant is claiming a method of using opioid receptors and not the receptors themselves, the claims recite a process for screening a substance's ability to bind to a mu opioid receptor. Therefore, in order to practice the claimed invention, one of ordinary skill in the art would need to be able to first identify a full-length mu opioid receptor which comprises at least 35 contiguous bases of SEQ ID NO:7. Given the only limitation that the receptor has to be encoded for by a nucleic acid molecule comprising these bases and include guanine 389, the artisan is not provided enough description as to what constitutes a mu opioid receptor. Polynucleotides encoding opioid receptors, including SEQ ID NO:7, are approximately 1600 bases in length. Therefore, to claim a method of using an opioid receptor by providing the limitation that it must comprise 35 of these 1600 bases is insufficient to demonstrate that Applicant was in possession of any of these receptors other than that encoded for by SEQ ID NO:7. Furthermore, the argument that the binding characteristics are not relevant since this receptor can bind antibody is also not persuasive for these reasons. If Applicant's intentions were to screen for antibodies, then the claim should be drawn to screening for the ability of an antibody to bind a fragment of a mu opioid receptor encoded for by 35 contiguous bases of SEQ ID NO:7. **However, without proper support, this would be considered new matter.** It is believed that all pertinent arguments have been addressed.

#### ***5. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement***

A. Claims 86-90, 92-99 and 101 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 6-8 of the Office Action dated 5/30/02. Applicant argues that the claimed process may identify antibodies which bind to an opioid receptor encoded for by 35 bases of SEQ ID NO:7 and that the function of the polypeptide is irrelevant. Applicant also argues that the preparation and use of a wide variety of opioid receptors comprising at least 35 contiguous bases of SEQ ID NO:7 was known to one skilled in the art.

These arguments have been considered, but are not deemed persuasive. The claims recite a process for screening a candidate opioid receptor for its ability to bind an opioid receptor, including a mu opioid receptor. The claims read on any full-length opioid receptor comprising at least 35 contiguous bases of SEQ ID NO:7. Regardless of whether or not the present invention is simply being used to identify antibodies which bind the receptor, the Applicant has provided no guidance and working examples of full-length opioid receptors other than that encoded for by SEQ ID NO:7, nor is it predictable

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to one of ordinary skill in the art how to make a functional opioid receptor given that the receptor only needs to comprise anywhere from 11-33 contiguous amino acids of SEQ ID NO:8 (i.e. 35-100 contiguous bases of SEQ ID NO:7). Therefore, then artisan would not know how to make a full-length receptor for use in the claimed method other than that encoded for by SEQ ID NO:7. For this reason, the function of the polypeptide is relevant since, again, the claims recite that the opioid receptor is a full-length receptor. Therefore, the breadth of the claims is excessive with regard to screening a candidate substance for its ability to bind to an opioid receptor encoded for by a nucleic acid molecule comprising at least 35, 45, 50, 75, or 100 contiguous nucleotides of SEQ ID NO:7, including the guanine at position 389 as well as to screening a candidate substance for its ability to bind to chimeric opioid receptors comprising said contiguous nucleotides. Again, if Applicant's intentions were to screen for antibodies, then the claim should be drawn to screening for the ability of an antibody to bind a fragment of a mu opioid receptor encoded for by 35 contiguous bases of SEQ ID NO:7. **However, without proper support, this would be considered new matter.** It is believed that all pertinent arguments have been addressed.

In summary, the breadth of the claims is excessive with regard to Applicants claiming a process for screening a candidate substance for its ability to bind to an opioid receptor encoded for by a nucleic acid molecule comprising only at least 35, 45, 50, 75, or 100 contiguous nucleotides of SEQ ID NO:7, including the guanine at position 389, as well as screening a candidate substance for its ability to bind to chimeric opioid receptors comprising said contiguous nucleotides. There is a lack of guidance and working examples of these nucleic acid molecules and proteins, as well as how to differentiate making mu opioid receptors from making non-mu opioid receptors. Applicants do not provide any language in the claims, or specification, which would allow the artisan to make a functional full-length opioid receptor, either mu or non-mu opioid receptors, by using as few as 35 contiguous bases of SEQ ID NO:7. The fact that the nucleic acid molecules encoding these receptors must comprise the guanine at position 389 of SEQ ID NO:7 is, itself, insufficient. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to differentially make a functional opioid receptor, as well as how to make both mu and non-mu opioid receptors, leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed. Claim 92 is rejected since it depends from rejected claim 86.

#### ***6. Claim Rejections - 35 USC § 112, second paragraph***

A. The rejection of claim 85 under 35 USC 112, second paragraph, has been withdrawn since the Applicant has amended the claim to remove the term "intrinsic activation."

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B. Claims 86-90, 92-99 and 101 remain rejected under 35 USC 112, second paragraph, for the reasons already of record on page 8 of the Office Action dated 5/30/02. Applicant argues that the word “including” modifies the phrase “at least 35 contiguous nucleotides of SEQ ID NO:7” to mean, for example, that the guanine at position 389 is included in the fragment. However, as Applicant argues, this is only an example. Therefore, the claim remains indefinite since it appears that guanine 389 does not have to be included in the fragment of “at least 35 contiguous nucleotides of SEQ ID NO:7.”

**7. Claim Rejections - 35 USC § 102**

A. The rejection of claims 83-85 under 35 USC 102 as being anticipated by Chen et al. has been withdrawn in view of Applicant’s arguments that the conception of the present invention was done solely by Dr. Yu.

**8. Conclusion**

A. Claims 83-85 are allowable.

B. Claims 86-90, 92-99 and 101 are rejected.

C. Claims 91 and 100 are objected to since they depend from rejected base claims. However, these claims would be allowable if rewritten in independent format and included all of the limitations of the base claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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***Advisory information***

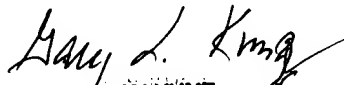
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
December 16, 2002

  
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